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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/762,641

04/01/2005

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

08/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/762,641	Applicant(s) ASAKAWA ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Magai et al. in view of Zhang et al. or Nabel et al.

The rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants traverse this rejection by asserting that Magai et al. and Zhang et al. and Nabel et al. are silent with regard to any disclosure that cells comprising Sendai virus lacking a M protein coding gene would be capable of introducing a transgene to a neighboring cell by contact infiltration. Applicants assert that while Magai et al. teach

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the M, F and HN components of Sendai virus, Magai et al. fails to disclose a role for the M, F or HN proteins in viral budding or cell fusion and therefore applicants assert that the ordinary skilled artisan would not have expected an M protein deficient Sendai virus RNA to be transferred to neighboring cells.

Applicants assert that the examiner has improperly used applicants' own disclosure to hypothesize the mechanism by which the M(-) Sendai viruses spread by cell-to-cell contact. Applicants indicate that the instantly disclosed mechanism for spreading of Sendai virus was unknown prior to the instant disclosure.

Applicants submit that the examiner's reasoning concerning spreading of the Sendai virus via contact infiltration being an inherent property is not proper. Applicants assert that obviousness cannot be predicated upon that which is unknown and that a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.

Applicant's arguments filed 4/30/08 have been fully considered but they are not persuasive. Applicants' arguments appear to be predicated upon the ordinary skilled artisan not being aware of the functions of the M, F or HN genes in the Sendai replication cycle and that said artisan would not have expected that the M(-) Sendai virus RNA (still possessing and expressing the F and HN proteins) could be transferred to neighboring cells. This assertion is perplexing since the Sendai virus was the prototype virus used in the early studies of virus infection mediated membrane fusion events. Indeed, the Sendai virus F protein (the F stands for **FUSION**), which is still present and expressed in the Sendai viral constructs disclosed by Magai et al., is the

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fusion protein of the Sendai virus and (along with the HN protein) mediates fusion between viral or cellular membranes comprising the F protein and cells which come into contact with said F protein. The ordinary skilled artisan in the area of recombinant viral genetics and membrane fusion studies (or even the artisan with only a cursory knowledge of viral fusion studies) would have been aware of the voluminous work on Sendai virus fusion mechanisms (**dating back to the late 1970's**) and would have had a thorough knowledge of the functions of the Sendai virus F, HN and M proteins. Applicants are encouraged to review the hundreds of prior art references dealing with analyses of the molecule biology of Sendai virus replication and the mechanisms by which the Sendai viral F and HN proteins function in viral replication and membrane fusion. Therefore, the ordinary skilled artisan would have known that the cells comprising the M(-) and F(+) and HN(+) Sendai viral constructs as disclosed by Magai et al. would have been able to fuse with other cells (by virtue of the expressed Sendai viral F and HN proteins) and hence be able to transfer the viral RNA (and transgenes) to the neighboring cell by contact infiltration.

Applicants argue that the examiner improperly used applicants own disclosure concerning the mechanism by which the M(-) deleted Sendai virus mediated contact infiltration. Applicants, in the instant disclosure (paragraph [0072]), postulate that the Sendai virus F and HN proteins mediate the fusion observed in the instant experiments described in the application. This observation by applicants concerning the ability of the Sendai virus F and HN proteins to mediate fusion is hardly a novel observation since the ability of Sendai viral F and HN proteins to mediate fusion events was well known

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for decades prior to applicant's invention. Since the Sendai viral F and HN proteins are also present in the (M-) Sendai viral construct containing cells disclosed by Magai et al., it must be assumed that said cells are also capable of transfer of Sendai viral RNAs by contact infiltration. Indeed, given the well known ability of the Sendai viral F and HN proteins to mediate cell fusion, it would be unreasonable for the ordinary skilled artisan to assume that contact infiltration would not occur in the cells disclosed by Magai et al.

With regard to applicants' indication that the examiner's reasoning concerning spreading of the Sendai virus via contact infiltration being an inherent property is not proper because obviousness cannot be predicated upon that which is unknown, it is noted that the decades of research on the ability of Sendai virus F and HN proteins to mediate fusion between cellular membranes argue against this property being unknown prior to applicants' invention.

References Cited But Not Applied:

The following references are cited, for applicants' benefit, as examples of the prior art dealing with Sendai virus F and HN protein mediated fusion mechanisms.

Aroeti et al., J. Biol. Chem., 1991, Vol. 266, No. 24, pp. 15845-15849.

Novick et al., PNAS, 1988. Vol. 85, pp. 7433-7437.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 22, 2008

/David Guzo/
Primary Examiner
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